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10/750,079	12/31/2003	Sepchr Fariabi	ACSG-66757 (0970CCC)	1878
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FULWIDER PATTON LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE, TENTH FLOOR LOS ANGELES, CA 90045			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/750,079

Applicant(s)

FARIABI, SEPEHR

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 57 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of U.S. Patent No. 6,827,734 in view of Palmaz (US 5,102,417). Claim 21 sets forth a stent including an alloy of cobalt, chromium, nickel, molybdenum, and optionally, tungsten, iron, and manganese. The percentages of these metals correspond to that of claim 57 because the optional ingredients are optional at 0%. However, claim 21 fails to disclose an undulating structure of independently expandable elements that can deform to a size suitable for holding open a coronary artery as set forth in claim 57. However, Palmaz teaches that it was known to fashion similar stents in the art into a plurality of connected independently expandable stents suitable for coronary artery implantation; see the front page, Figures 8 to 10, and column 5, lines 1-44. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to form the device set forth in

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claim 21 into the form disclosed by Palmaz so that it could be utilized to treat coronary arteries with extended length blockages.

Claim 57 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,419,693 in view of Palmaz (US 5,102,417). Claim 1 sets forth a stent including an alloy of cobalt, chromium, nickel, and optionally, molybdenum, tungsten, and iron. The percentages of these metals corresponds to that of claim 57 because the optional ingredients are optional at 0%, but molybdenum can be used up to 12% that closely corresponds to the "up to about 15%" as set forth in present claim 57. However, claim 1 fails to disclose an undulating structure of independently expandable elements that can deform to a size suitable for holding open a coronary artery as set forth in claim 57. However, Palmaz teaches that it was known to fashion similar stents in the art into a plurality of connected independently expandable stents suitable for coronary artery implantation; see the front page, Figures 8 to 10, and column 5, lines 1-44. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to form the device set forth in claim 1 into the form disclosed by Palmaz so that it could be utilized to treat coronary arteries with extended length blockages.

Claim 57 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,636,641 in view of Palmaz (US 5,102,417). Claim 1 sets forth an elongated member including an alloy of cobalt, chromium, nickel, and optionally, molybdenum, tungsten, and iron. The percentages of these metals corresponds to that of claim 57 because the optional

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ingredients are optional at 0%, but molybdenum can be used "up to about 12%" that closely corresponds to the "up to about 15%" as set forth in present claim 57. However, claim 1 fails to disclose an undulating structure of independently expandable elements that can deform to a size suitable for holding open a coronary artery as set forth in claim 57. However, Palmaz teaches that it was known to fashion similar stents in the art into a plurality of connected independently expandable stents suitable for coronary artery implantation; see the front page, Figures 8 to 10, and column 5, lines 1-44. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to form the device set forth in claim 1 into the form disclosed by Palmaz so that it could be utilized to treat coronary arteries with extended length blockages.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37 to 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original support for the new language of claims 37 to 43 that states that the cylindrical elements of the stent "assume the first low profile delivery configuration through compression"; see claim 37, lines 10-11. The Applicant did not cite any portion of the specification for support, and

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the Examiner did not see explicit or implicit support for the new limitation. On page 8, lines 19-25, "compression" is used in connection with keeping self-expanding nickel-titanium stent small via compression.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: As an alternative to the previous paragraph, the new language of claim 37 does not have antecedent basis from the specification. Even if Applicant can show that there is implicit support for such language, he would also have to amend the specification to give the language clear antecedent basis as required by 37 CFR 1.75(d)(1).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

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published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 37-49, 53, 56-61, 72-74, 78-80, and 83 are rejected under 35 U.S.C. 102(e) as being anticipated by Robinson et al (US 5,891,193) where the stent of Robinson has a relaxed state where it will not self expand, but it is capable of being bent (permanently deformed) to form the stent; see column 5, lines 31-51. Therefore, the stent is plastically deformable and could be expanded to a state where there would be no bends in the wires; this unbent expanded diameter reads on the "diameter suitable to hold open the coronary artery" as claimed. Particularly, the size of a coronary vessel varies depending upon the particular patient being treated, and thus, the size of the device as claimed is met by Robinson's device which is also balloon expandable to an unbent form of the segments (33). The unbent form and the other forms thereof are the size of some individuals.

Furthermore, the claimed alloy the claimed stent is the same material (MP35N from Carpenter Technology) as that of Robinson's device, which is also MP35N; see Robinson on column 5, lines 34-38 and see the present specification on page 13. For this reason, the claimed alloy composition is fully met. Moreover, since Robinson utilizes the same percentages as the presently claimed invention to make their device, it flows from this that it also has the same properties of expandability.

Additionally, self-expansion depends upon how the device is used and how it is biased. For this reason, the Examiner maintains that the claim language is read on by Robinson's device as it is disclosed.

With regard to the new limitations of claim 37, due to the fact that permanent bends can be put in the wires of Robinson, the Examiner asserts that there is inherently a state of compression that would plastically deform the stent of Robinson since the low profile configuration has no limit and includes placing a plastically deforming amount of pressure on the stent to compress it.

With regard to claim 42, it was noticed that the range of 0 to 20% iron is being claimed, and thus, Robinson meets this limitation because they disclose a 0% iron alloy.

With regard to claim 59, Applicants are directed to Figure 2 of Robinson.

With regard to claims 60 and 61, the aspect ratio claimed is considered to be broad because it is associated with the modifier "about." For this reason and upon inspection of Robinson's figures, the Examiner determined that the claimed aspect ratios claimed are met by Robinson; see Figure 2, which is read on by the present claim language for claim 60 and see Figure 4 for the ratio of two to one.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 51 and 52 are rejected under 35 U.S.C. 103 as being unpatentable over Robinson et al (US 5,891,193) in view of Hillstead (US 4,856,516) or Tower (US 5,217,483). Robinson et al meets the claim language except for the transverse



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diameter of about 0.003 inches. However, Hillstead (see column 3, lines 43-45) and Tower (see column 2, lines 34-43) both disclose stents constructed of wires having a diameter (which would be the transverse diameter) of about 0.003 inches. Hence, it is the Examiner's position that it would have been obvious to construct the Robinson device with wires of about 0.003 inches for the same reasons that Hillstead and Tower do the same and in order have a low profile for the stent.

Claims 54, 62-71, 75, 76, 81, 82, 84, and 85 are rejected under 35 U.S.C. 102(e) as anticipated by Robinson et al (US 5,891,193) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Robinson et al (US 5,891,193) alone.

With regard to claims 54, 62-71, and 75, the electrochemical polishing step is considered to be a product-by-process limitation. Since the degree that this step is performed is not specified, the Examiner posits that it would not result in a product that is different than that disclosed by Robinson; see MPEP 2113, which is incorporated herein by reference. Alternatively, the Examiner asserts that the claimed invention, if different, is only slightly different. For this reason, the claim language is considered to be at least clearly obvious in view of Robinson alone.

With regard to claims 70 and 71, the aspect ratio claimed is considered to be broad because it is associated with the modifier "about." For this reason and upon inspection of Robinson's figures, the Examiner determined that the aspect ratios claimed are met by Robinson.

With regard to claims 68, 69, and 76, the cold working or age hardening step is considered to be a product-by-process limitation. Since the degree that this step is

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performed is not specified, the Examiner posits that it would not result in a product that is different than that disclosed by Robinson; see MPEP 2113, which is incorporated herein by reference. Alternatively, the Examiner asserts that the claimed invention, if different, is only slightly different. For this reason, the claim language is considered to be at least clearly obvious in view of Robinson alone.

With regard to claims 84 and 85, the step of cutting voids from a member is considered to be a product-by-process limitation. Since Robinson also discloses a stent with voids therein, the Examiner posits that process of cutting would not result in a product that is different than that disclosed by Robinson; see MPEP 2113, which is incorporated herein by reference. Alternatively, the Examiner asserts that the claimed invention, if different, is only slightly different. For this reason, the claim language is considered to be at least clearly obvious in view of Robinson alone.

Claims 55 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al (US 5,891,193) in view of Bokros (US 4,300,244). Robinson meets or renders obvious the claim language as explained in the rejection of claim 54 above, but fails to disclose the use of a biocompatible coating thereon. However, Bokros teaches that it was known to coat similar cardiovascular implants with biocompatible coating in order to render them more biocompatible; see column 2, lines 16-24. Therefore, it is the Examiner's position that it would have been obvious to coat the Robinson device with a biocompatible coating to make it more biocompatible.

Claim 50 is rejected under 35 U.S.C. 103(a) as obvious over Robinson et al (US 5,891,193) alone. Robinson meets the claim language except for the percentage of

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nickel claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize a 2% nickel alloy because Applicants have not disclosed that doing so provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well as a stent. Therefore, it would have been an obvious matter of design choice to modify Robinson to obtain the invention as specified in the claims.

### ***Response to Arguments***

Applicant's arguments filed April 23, 2007 have been fully considered but they are not persuasive.

Applicant traverses the double patenting rejections by arguing that there are features in the present claims that are patentably distinct from those set forth in the patented claims. However, the Examiner asserts that the present claims are not patentably distinct from the patented claims because Palmaz, as newly applied, teaches that these features were well known to the art. In particular, the argument that there is no plastic deformation claimed in the patented claims is made. However, the examiner asserts that at least Palmaz teaches the argued features were known to the art. Furthermore, the fact that the same materials are claimed in both sets of claims, the Examiner asserts that it flows from this that the claimed features are inherently present.

The Applicant also traverses the Robinson rejections by arguing that since Robinson does not disclose deforming the stent in the manner suggested by the claimed functional language that the claim language is not met. This has not been

found persuasive because Robinson, as explained by the Examiner, inherently implies that such deformation is necessarily present therein; see the explanation of the rejection. For this reason, the Examiner asserts that the claim language is fully met; see MPEP 2112 that is incorporated herein by reference.

In response to applicant's argument that Robinson is not shown being utilized in the manner claimed, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be

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applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/  
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Art Unit 3738